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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,224	08/02/2001	Andrea W. Chow	01-051710US	7230
22798	7590	03/23/2004	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,224

Applicant(s)

CHOW ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 37-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/3/2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 – 36, drawn to a microfluidic apparatus, classified in class 422, subclass 100.
- II. Claims 37 – 51, drawn to a method of distributing fluids, classified in class 222, subclass 630.
- III. Claims 52 – 55, drawn to a method of fabricating a manifold, classified in class 156, subclass 60.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the product can be utilized to distribute fluid from the ports of the manifold. Furthermore, the product does not require the microchannel network to be in fluid communication with a plurality of ports.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be utilized to make a manifold not having or utilizing a microfluidic body structure.

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Inventions III and II are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). However, because a distinction has been shown between the product and either of the process of making or process of using, an election of either process groupings will not result in an examination of the product claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Christopher Sappenfield on 11/10/2003 a provisional election was made without traverse to prosecute the invention of group I, claims 1 - 36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 37 - 55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

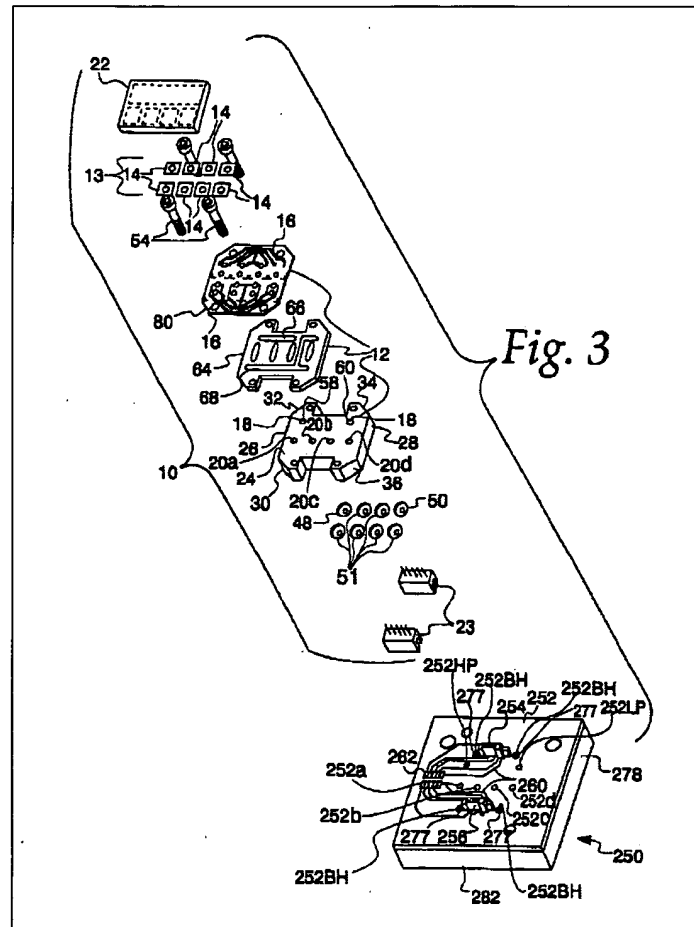
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

1. Claims 1 – 7, 9 and 14 – 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Packard *et al.* (U.S. Pat. No. 5,640,995 A). Regarding claims 1 – 6, 9, 14 – 16 and 23 – 26, Packard *et al.* teach an apparatus comprising: a body structure (80) comprising at least one microchannel network and a plurality of ports disposed in the body structure; and a manifold (64) comprising at least one channel network and at least one aperture disposed in the manifold, wherein the manifold is mated with the body structure (see col. 8, line 41 – col. 10, line 67; figures 1 – 11).



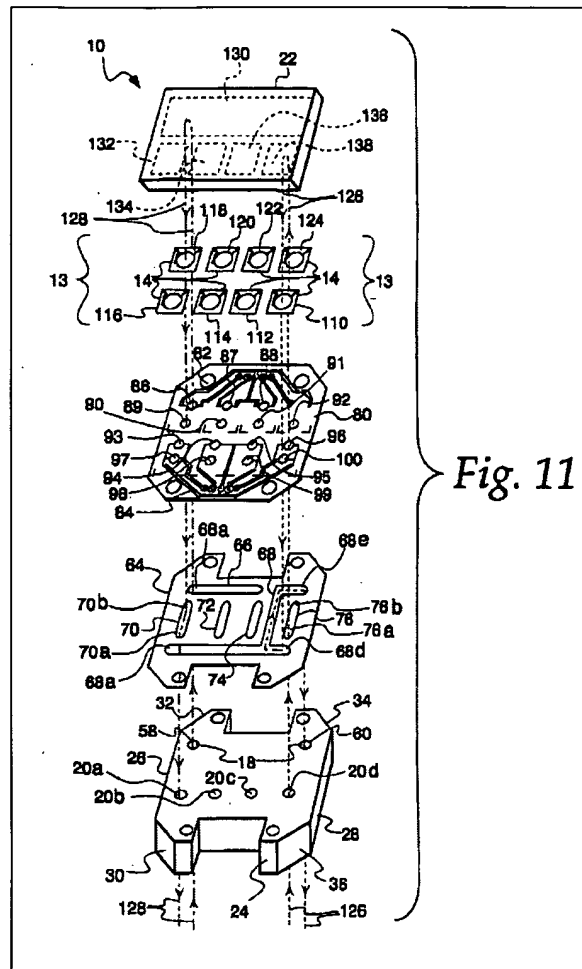


Fig. 11

Regarding claim 7, this claim recites process or intended use limitations, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. For example, claim 7 recites how the apparatus is to be operated, such as using a bulk viscosity enhancer solution or electrolyte solution disposed within the apparatus. These recitations do not impart any limitations to define the structure of the apparatus itself being claimed. Process limitations do not add patentability to a structure, which is not distinguished

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from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

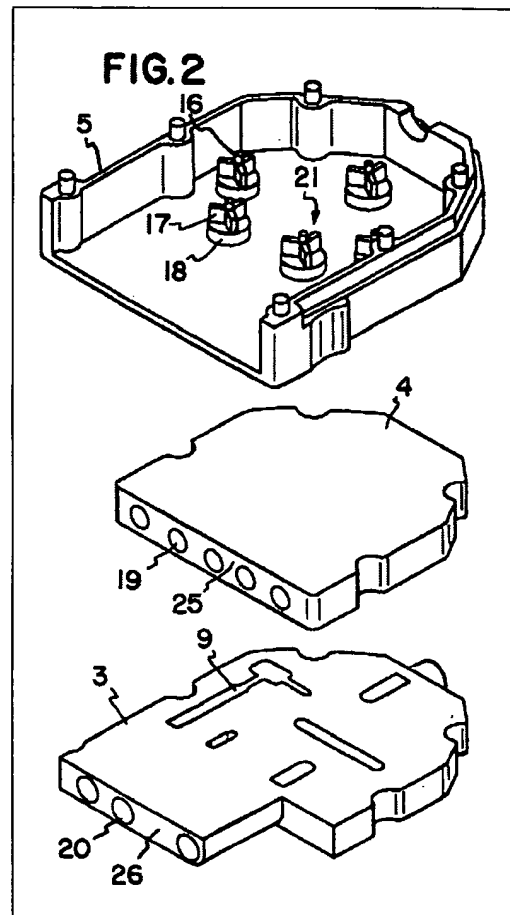
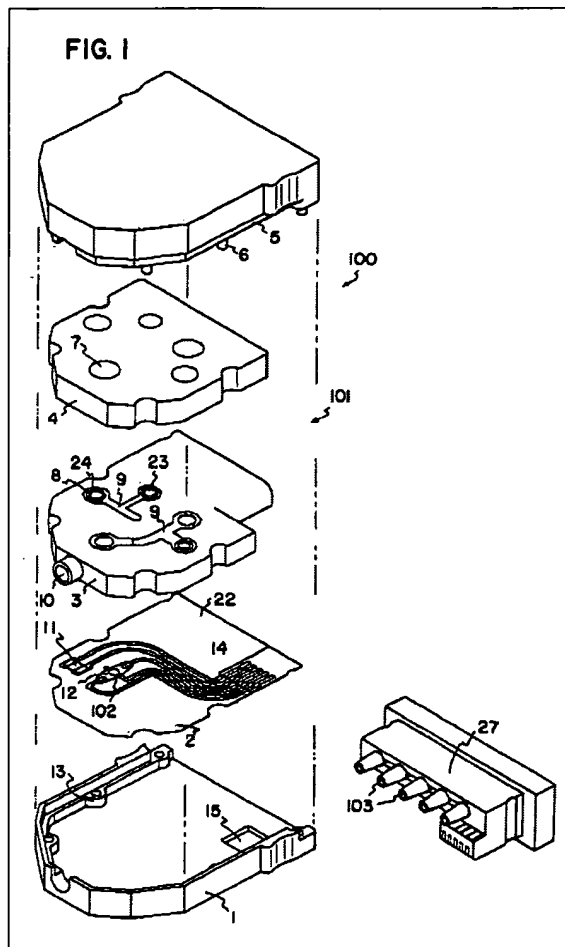
Regarding claims 17 and 18, Packard *et al.* teach the incorporation of a fluid pressure force modulator, such as microactuators (14), and a gravity force modulator, such as a pressure inlet (58) or vacuum outlet passage (60) (see col. 8, lines 51 – 65). Regarding claim 19, Packard *et al.* teach the incorporation of an alignment structure, such as the bottom surface of the body structure (80), for aligning or placing the body structure (80) on the surface of the manifold (64) (see figures 3 & 11). Regarding claim 20, Packard *et al.* teach the incorporation of a membrane portion for pneumatic actuation (see col. 13, lines 9 – 21). Regarding claims 21, 29 and 36, these claim recite specific fabrication processes for making the claimed apparatus. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re*

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Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113). Regarding claim 22, Packard *et al.* teach the incorporation of O-rings and adhesive gaskets (see col. 9, line 19 – col. 10, line 18). Regarding claim 27, Packard *et al.* teach a pair of inlet or outlet O-rings (48 & 50) are seated, respectively, within bores (40 & 42) (see col. 9, lines 20 – 40). Packard *et al.* further teach the incorporation of electrical traces, such as conductive coatings, on each of the circuit boards, which connect microvalves (see col. 17, lines 5 – 62). Regarding claims 28 and 35, Packard *et al.* teach that the apparatus may comprise a layered structure (see col. 8, lines 41 – 67; figure 3). Regarding claims 30 and 31, Packard *et al.* teach that the apparatus may be fabricated using ceramic and polycarbonate materials (see col. 9, lines 9 – 19).

2. Claims 1 – 8, 13 – 21, 23 – 26, 28 – 30, 32 – 34 and 36 are rejected under 35

U.S.C. 102(e) as being anticipated by Say *et al.* (U.S. Pat. No. 6,117,290 A). Regarding claims 1 – 6, Say *et al.* teach an apparatus comprising: a body structure (assembly 100) comprising at least one microchannel network (9) and a plurality of ports (20) disposed in the body structure; and an associated manifold portion (27) comprising apertures (103), which mates with the body structure (see col. 5, lines 23 – col. 6, line 64; figures 1, 2 & 5).



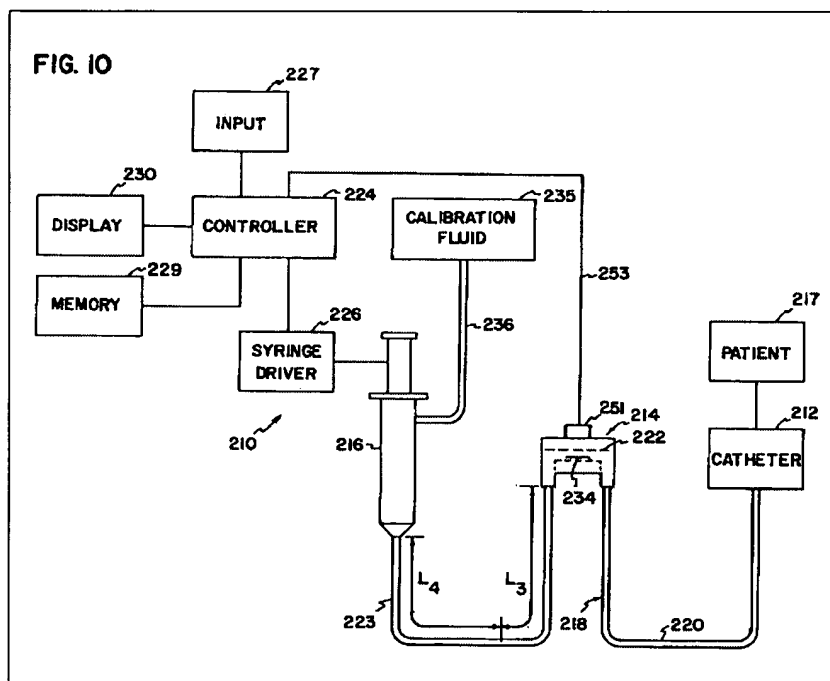


Regarding claim 7, this claim recites process or intended use limitations, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. For example, claim 7 recites how the apparatus is to be operated, such as using a bulk viscosity enhancer solution or electrolyte solution disposed within the apparatus. These recitations do not impart any limitations to define the structure of the apparatus itself being claimed. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a

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structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding claim 8, Say *et al.* teach the incorporation of a controller (224) and a detector apparatus (214) (see col. 8, lines 17 – 37; figure 10).



Regarding claim 13, *Say et al.* teach that the apparatus may be programmed or automated (see col. 7, lines 31 – 33). Regarding claims 14 – 16, 23 – 26, 28 and 32 – 34, *Say et al.* teach that the manifold and the body structure may be connected together or integrated (see col. 5, lines 32 – 36; col. 6, lines 31 – 39; figures 1 – 4). Regarding claims 17 and 18, *Say et al.* teach the incorporation of a fluid pressure force modulator, such as a pneumatic valve actuator (4), and a gravity force modulator, such as a valve structure (24) and a pressure compensating structure (21) (see col. 6, lines 9 – 31). Regarding claim 19, *Say et al.* teach the incorporation of an alignment structure, such as the side edges of the manifold portion (27) (see figure 1). Regarding claim 20, *Say et al.* teach the incorporation of a membrane (28) held in contact with the valve structure (24) by a pressure compensating structure (21) (see col. 6, lines 17 – 31; figures 1 & 2). Regarding claims 21, 29 and 36, these claim recite specific fabrication processes for making the claimed apparatus. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113). Regarding claims 30 and 36, *Say et al.* teach that the apparatus may comprise an injection molded polymer material (see col. 6, lines 45 – 49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 – 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say *et al.* Regarding claims 9 and 11, Say *et al.* do not specifically teach the use of an additional manifold or body structure. However, Say *et al.* do teach that their disclosed apparatus is used for providing on-line monitoring/measurement of bioanalytes in a patient (see col.4, lines 49 – 53). It is notoriously well known in the art of clinical diagnostics that sterile instruments be used with each patient (see MPEP § 2144.03). Consequently, a person of ordinary skill in the art would accordingly have recognized the desirability of using another manifold or body structure with the apparatus disclosed by Say *et al.*, in order to facilitate the replenishment of reagents without compromising apparatus sterility and thereby avoid endangering the patient. Furthermore, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of a person of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of two or more manifolds, which interchangeably mates with the body structure of the claimed apparatus. Similarly, it would have been obvious to a person of ordinary skill in the art to incorporate the use of two or more body structures, which interchangeably mates with the manifold of the claimed apparatus. Regarding claims 10 and 12,

Say *et al.* teach the incorporation of a controller (224) and a detector apparatus (214) (see col. 8, lines 17 – 37; figure 10).


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kercso *et al.* teach high-throughput microfluidic systems and methods. Chow *et al.* teach controller/detector interfaces for microfluidic systems. Chow *et al.* further teach multi-layer microfluidic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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